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| EXAMINER | |
|---|---|
| JEAN-LOUIS, SAMIRA JM | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,509 | COELINGH BENNINK ET AL. | |
| | Examiner | Art Unit | |
| | SAMIRA JEAN-LOUIS | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) *17,21-23,25,27 and 29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20, 24, 26, 28 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

This Office Action is in response to the amendment submitted on 09/26/08. Claims 17-32 are currently pending in the application, with claims 1-16 having being cancelled and 21-23, 25, 27, and 29-31 having been withdrawn. Accordingly, claims 18-20, 24, 26, 28, and 32 are being examined on the merits herein.

Receipt of the aforementioned amended claims, amended abstract and declarations of Drs. Speroff, Westhoff, Strauss, and Coelingh Bennik is acknowledged and has been entered.

The Examiner further acknowledges withdrawal of the objection to the abstract given the deletion of the legal phraseology "comprising". As for the information disclosure statement, the Examiner refers Applicant to page 3 of the Office Action dated 03/26/08 which clearly states on the record that the abstract of WO 00/62753 has been considered.

Applicant's argument with respect to the rejection of claim 28 under 35 U.S.C. § 112, first paragraph for a method of preventing vaginal dryness has been fully considered but is not found persuasive. First, the Examiner asserts the fact that the

term "prevention" was given its broadest interpretation since Applicant provided no clear definition. Consequently, in light of the definition of the term "preventing" (i.e. to keep from ever happening) and the lack of enabling disclosure on prevention of vaginal dryness, the Examiner contends that the method of preventing vaginal dryness is non-enabling. Second, given that vaginal dryness can be the result of menopause, and menopause is a physiological condition that typically occurs in women as a result of the loss of estrogen, applicant provided no reasonable enablement to prevent vaginal dryness from such physiological effects. Third, applicant's specification provides no direction or guidance for a method of preventing vaginal dryness by applying 5 µg/g of an estrogenic component with a cosmetic acceptable vehicle. Consequently, absent of experimental evidence, the Examiner asserts that no one skilled in the art would accept that the instantly claimed estrogenic compounds could predictably be used to prevent vaginal dryness without undue experimentation. However, if Applicant believes otherwise, it is incumbent upon applicant to demonstrate that the instantly claimed estrogenic compounds of the invention do indeed ***prevent*** vaginal dryness. Thus, the rejection of claim 28 under 35 U.S.C. § 112, first paragraph is still deemed proper.

Applicant's traversal of the rejection of claim 28 under 35 U.S.C. § 112, first paragraph for failure to comply with the written description requirement has been fully considered. Given that applicant has amended the claims to now reflect a general formula wherein the C18 position is occupied by a methyl group, such rejection is now

moot. Consequently, the rejection of claim 28 under 35 U.S.C. § 112, first paragraph is hereby withdrawn.

Applicant's argument that Kragie teaches a broad list of estrogen function replacement agents and not particularly estetrol has been fully considered. Applicant along with the aforementioned declarations further argue that since estetrol is not pharmacologically active, one of ordinary skill in the art would not have the motivation to pick estetrol from the long list of Kragie. Such arguments are not persuasive since Kragie specifically teaches compositions containing estrogen function replacement (EFR) agents that can replace the role of estrogens such as estradiol in the functions of humans (see abstract and pg. 2, paragraph 0013). Additionally, Kragie provides a definition for such EFR agents wherein the agent can either selectively, partially, or totally replace the function of estrogen compounds (see pgs. 3-4, paragraph 0033). Importantly, Kragie teaches that examples of EFR agents include a variety of estrogen compounds including estetrol (i.e. applicant's elected species). Thus, regardless of the binding affinity of estetrol to the Estrogen receptor or the pharmacological activity of estetrol, and in view of Kragie who teaches the use of a selective, total, or *partial* agent to replace estradiol, one of ordinary skill would have indeed found it *obvious to try* estetrol since Kragie teaches that EFR agents can be used in the treatment of urogenital and/or vaginal atrophy (see pg. 8, paragraph 0073). Thus, in view of KSR, the Examiner contends that Kragie did indeed suggest a finite number of identified, predictable potential solutions (i.e. EFR agents) to the recognized need or problem (i.e.

vaginal and/or urogenital atrophy) and therefore one of ordinary skill in the art would have indeed been motivated to pursue the known potential solutions with a reasonable expectation of success. KSR, 550 U.S. at ___, 82 USPQ2d at 1397. Willhite, on the other hand, was provided to demonstrate that urogenital atrophy is also known as vaginal dryness. Thus, one of ordinary skill in the art would have indeed found it obvious to try estetrol as an EFR agent in the treatment of urogenital atrophy or vaginal dryness with the reasonable expectation of obtaining a method that is efficient in treating urogenital atrophy and its associated symptoms. Consequently, the Examiner asserts that the rejection of claim 28 under 35 U.S.C. § 103 (a) was indeed proper.

Applicant's argument that estetrol was unexpectedly found pharmacologically active has again been fully considered but is not found persuasive. Again, the Examiner refers applicant to the aforementioned argument that Kragie explicitly teach the use of EFR agents in the treatment of urogenital atrophy, also known as vaginal dryness. Moreover, Kragie teaches various EFR agents including estetrol. Thus, in view of the teachings of Kragie and in view of the definition of urogenital atrophy, one of ordinary skill in the art would have indeed found it obvious to try estetrol to treat vaginal dryness. Irrespective of applicant's claims of estetrol's newly discovered pharmacological activity, the Examiner contends that prior to applicant discovery, one of ordinary skill in the art would have indeed found it obvious to try estetrol in the treatment of vaginal dryness since Kragie teaches the use of selective, total, and partial EFR agents (i.e. including estetrol) in the treatment of urogenital atrophy (i.e. vaginal

dryness). Thus, it is the Examiner's contention that Kragie does indeed render obvious applicant's invention.

However, in view of applicant's amendment, the following modified 112, first paragraph and 103 (a) Final rejections are being made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20, 24, 26, 28, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating vaginal dryness, does not reasonably provide enablement for a method to prevent vaginal dryness. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Importantly, given that the term "prevention" implies an absolute term, it is assumed that vaginal dryness cannot be absolutely prevented at this time given the unpredictability of the art and lack of guidance from applicant's specification. Particularly, applicant does not reasonably provide enablement for a method to prevent vaginal dryness as vaginal dryness can result from menopause due to low estrogen level and menopause is a biological event that cannot be absolutely

prevented. Additionally, the application does not enable any person skilled in the art to use the invention to prevent vaginal dryness.

The instant claims are drawn to a method of treating or preventing vaginal dryness by applying at least a 5 µg/g of an estrogenic component of a formula and a cosmetically acceptable vehicle. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention as claimed.

Attention is directed to *In reWands,* 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method of treating or preventing vaginal dryness by applying at least a 5 µg/g of an estrogenic component of a formula and a cosmetically acceptable vehicle. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites the above fact wherein vaginal

dryness is a symptom of menopause which cannot be prevented.

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term "prevention", the examiner will adopt the broadest reasonable interpretation for same. Webster's Ninth New Collegiate Dictionary defines "prevention" as "to keep from happening or existing", i.e., to completely eradicate.

The claims are thus very broad insofar as they recite the "prevention" of vaginal dryness, i.e., the complete eradication of same. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for a method for preventing vaginal dryness by applying at least a 5 µg/g of an estrogenic component of a formula and a cosmetically acceptable carrier. In fact, applicant provided no guidance for the prevention of vaginal dryness only guidance to the treatment of said condition.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed estrogenic compounds could be predictably used to prevent vaginal

dryness as inferred by the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation in order to determine if said estrogenic component claimed by applicant can in fact prevent vaginal dryness, with no assurance of success.

Genentech, 108 F.3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, a method for preventing vaginal dryness comprising applying at least a 5 µg/g of an estrogenic component of a formula and a cosmetically acceptable carrier is not considered to be enabled by the instant specification.

The claims are examined herein for a method of treating vaginal dryness.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 18-19, 24, 26, 28 and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kragie (U.S. 2004/0192598 A1, previously cited) in view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited).**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Kragie teaches the use of compositions that can replace the role of estrogens in the functions of humans (see abstract). According to Kragie, the compositions comprise estrogen function replacement agent (s) (EFR) that can selectively, partially, or totally replace the function of estrogens, such as estradiol, in the functions of humans and animals (see pg. 2, paragraph 0013 and pg. 4, paragraph 0033). Examples of such agents include derivatives of estradiol such as estetrol (i.e. a compound of the aforementioned formula which reads on claim 28; see pg. 4, paragraph 0038 and pg. 11, claim 7). The dosage of the EFR is provided for sufficient biological activity for the

desired estrogen function at the tissue target and needs to minimally meet the EC50 value (half maximal efficacy concentration; instant claim 24) for the desired estrogen function (see pg. 5, paragraph 0044) and can be administered with a suitable carrier (see pg. 6, paragraph 0051). Kragie further teaches that the compositions may be formulated for topical or transdermal applications in the form of lotions, gels, or creams and when applied as a transdermal patch for a period of 1 to 4 days wherein the patch contacts the active ingredient to a smaller surface area allowing a slow and constant delivery of the active ingredient (i.e. application more than once a day; instant claims 26 and 32; see pg. 6, paragraph 0051). Of interest, Kragie described the EFR agents containing compositions as useful for menopause and further teach that EFR agents are currently used in perimenopausal and post-menopausal women for treatment of vaginal atrophy and urogenital atrophy (see pg. 8, paragraph 0073).

Kragie does not particularly teach a method of treating vaginal dryness using at least 5 µg/g of estetrol. However, to one of ordinary skill in the art, it would have been obvious to optimize the appropriate dosage that would produce the desired estrogenic function.

Moreover, it is generally noted that differences in concentration or range do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456,

105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or dosages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum combination of dosages.

Willhite et al. has been provided to demonstrate that urogenital atrophy is also known as vaginal dryness (see Introduction Section). Consequently, Kragie necessarily meets the limitation of claim 28 and teaches a method of treating vaginal dryness.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize the method of Kragie with a desired amount of estetrol in the treatment of vaginal dryness since Kragie teaches the use of estradiol derivatives such as estetrol in amounts that would produce the desired estrogenic function for the treatment of urogenital atrophy. Given that Kragie teaches the use of ERF agents to treat urogenital atrophy (i.e. vaginal dryness as disclosed by Willhite et al.) using ERF agents such as estetrol, one of ordinary skill would have been motivated to utilize estetrol to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in treating vaginal dryness and efficacious in producing desirable estrogenic function.

**Claim 20 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Kragie (U.S. 2004/0192598 A1, previously cited) in view of Willhite et al.**

**(Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited) as applied to claims 18-19, 24, 26, 28, and 32 and in further view of Younglai et al. (J. of Clinical Endocrinology and Metabolism, 1968, Volume 28, Issue 11, pgs. 1611-1617).**

The Kragie and Willhite references are as discussed above and incorporated by reference herein. However, Kragie and Willhite do not teach the precursors of the estrogenic compound of claim 28 containing acyl radical moieties.

Younglai et al. teach that estetrol (i.e. E4) has many precursors (see pg. 1617, figure 2). In fact, Younglai et al. teach 15-α-hydroxyandrostenedione or dehydroxyandrostenedione as precursors of E4 and containing acyl moiety group (instant claim 20).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize dehydroxyandrostenedione and 15-α-hydroxyandrostenedione as precursors of E4 since Younglai et al. teach them as precursors of E4. Given the teachings of Kragie, Willhite, and Younglai, one of ordinary skill would have been motivated to utilize estetrol derived from 15-α-hydroxyandrostenedione or dehydroxyandrostenedione to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in treating vaginal dryness and efficacious in producing desirable estrogenic function.

**Claims 18-19, 24, 26, 28, and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sitruk-Ware et al. (Shweiz. Rundsch, Med. Praxis, 1997,**

**Vol. 86, No. 33, pgs. 1-13, English Translation) in view of Spicer (U.S. 5,211,952, previously cited) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited).**

Sitruk-Ware et al. teach that urogenital symptoms is due to low estrogen after menopause (see pg. 2, paragraph 1). This low estrogen is further taught to lead to urogenital atrophy, vaginal irritation and vaginal dryness wherein Sitruk-Ware et al. suggest the use of estrogen to be applied to the vaginal surface to treat such symptoms (see pg. 2, paragraphs 2-3, pg. 3, paragraph 2, and pg. 4, paragraph 2). Sitruk-Ware et al. further teach that estrogenic treatment at doses necessary for making the symptoms disappear is an efficient way to correct the aforementioned symptoms (see pg. 2, paragraphs 2-4, pg. 4, paragraph 2, and pg. 10, paragraph 2). Different modes of application have been developed including vaginal creams (instant claim 32, pg. 2, last paragraph). Sitruk-Ware et al. further teach that treatments with low adverse effects and low doses are preferred (pg. 10, paragraph 4). Sitruk-Ware et al. further teach estrogen compounds at low doses such as 7.5 µg/day for prolonged release regimen in the treatment of urogenital atrophy (pg. 8, paragraph 1).

The Willhite and Sitruk-Ware et al. references are as discussed above and incorporated by reference herein. However, Sitruk-Ware and Willhite do not address the use of an estrogenic component such as estetrol.

Spicer et al. teach preparations for use for extended period of time comprising gonadotrpopins (GnRH) and estrogenic compounds (see col. 1, lines 9-11). Spicer et al. further teach the addition of estrogenic steroids for counteracting the possibility of side effects such as urogenital atrophy which may develop during prolonged therapy (col. 3, lines 25-46). Estrogenic steroids such as estetrol may be employed in the composition for a short term administration on the order of about 5 to 20 days and formulated for vaginal delivery (instant claims 26 and 28; col. 5, lines 49-53, and 60, and col. 6, line 68). These compositions can further include a carrier vehicle known for controlled release (see col. 7, lines 1-5).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Spicer et al. in view of their efficacy in combating urogenital atrophy since Willhite et al. teach that vaginal dryness is also known as urogenital atrophy. Moreover, one of ordinary skill in the art would have found it obvious to formulate the composition of Spicer et al. as a vaginal cream since Sitruk-Ware et al. teach that creams are conventional formulations in the treatment of vaginal atrophy. Thus, given that Sitruk-Ware et al. teach a method of treating vaginal dryness or urogenital atrophy, and Spicer et al. teach the use of estrogenic compound such as estetrol for combating urogenital atrophy, and Willhite et al. teach that urogenital atrophy is vaginal dryness, one of ordinary skill would have been motivated to utilize the composition of Spicer et al. at a dose of at least 7.5 μg/day of an estrogenic compound as taught by Spicer et al. to treat vaginal dryness as disclosed by Sitruk-

Ware et al. and use estetrol as the preferred compound in light of the disclosure of Spicer et al. with the reasonable expectation of providing a method that is efficacious in counteracting GnRH side effects including vaginal dryness.

**Claim 20 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Sitruk-Ware et al. (Shweiz. Rundsch, Med. Praxis, 1997, Vol. 86, No. 33, pgs. 1-13, English Translation) in view of Spicer (U.S. 5,211,952, previously cited) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited) as applied to claims 18-19, 24, 26, 28, and 32 and in further view of Younglai et al. (J. of Clinical Endocrinology and Metabolism, 1968, Volume 28, Issue 11, pgs. 1611-1617).**

The Sitruk-Ware and Willhite references are as discussed above and incorporated by reference herein. However, Sitruk-Ware and Willhite do not teach the precursors of the estrogenic compound of claim 28 containing acyl radical moieties.

Younglai et al. teach that estetrol (i.e. E4) has many precursors (see pg. 1617, figure 2). In fact, Younglai et al. teach 15-α-hydroxyandrostenedione or dehydroxyandrostenedione as precursors of E4 and containing acyl moiety group, both of which contain an acyl group moiety (instant claim 20; pg. 1616, right col.).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize dehydroxyandrostenedione and 15-α-hydroxyandrostenedione as precursors of E4 since Younglai et al. teach them as precursors of E4. Given the teachings of Sitruk-Ware, Willhite, and Younglai, one of ordinary skill would have been motivated to utilize estetrol derived from 15-α-hydroxyandrostenedione or dehydroxyandrostenedione to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in counteracting GnRH side effects including vaginal dryness.

## *Conclusion*

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

12/29/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617